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WE CLAIM:

Sub 5
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1. A controlled-release glucosamine composition comprising a therapeutically effective amount of a glucosamine component dispersed in a controlled-release matrix system capable of releasing said glucosamine in an amount and at a rate sufficient to maintain an effective glucosamine blood serum level over a designated time period, said controlled-release matrix system comprising a controlled-release component which comprises at least one water soluble cellulose polymer.

10 2. A controlled-release glucosamine composition of Claim 1, wherein said glucosamine component is selected from the group consisting of N-acetyl-D-glucosamine, glucosamine hydrochloride, glucosamine sulfate and mixtures thereof.

15 3. A controlled-release glucosamine composition of Claim 2, wherein a daily dosage of said glucosamine ranges from about 2 mg to about 45 mg per kilogram of body weight.

20 4. A controlled-release glucosamine composition of Claim 3, wherein said daily dosage is from about 14 mg to about 29 mg per kilogram of body weight.

5. A controlled-release glucosamine composition of Claim 4, wherein said daily dosage is about 21 mg per kilogram of body weight.

25 6. A controlled-release glucosamine composition of Claim 1, wherein said controlled-release component comprises at least one water soluble high molecular weight cellulose polymer.

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7. A controlled-release glucosamine composition of Claim 1, wherein said controlled-release component is selected from the group consisting of hydroxypropyl methyl

7/ 8. A controlled-release glucosamine composition of Claim ~~7~~⁶, wherein said controlled-release component is HPMC.

8/ 9. A controlled-release glucosamine composition of Claim ~~8~~⁷, wherein said HPMC is a high molecular weight HPMC.

9/ 10. A controlled-release glucosamine composition of Claim ~~9~~⁸, wherein said HPMC consists of fine particulates having a particle size such that not less than 80% of the HPMC particles pass through an 80 mesh screen and said HPMC is present in an amount from about 8 to about 12wt%, based upon total weight of the composition.

10/ 11. A controlled-release glucosamine composition of Claim 1, wherein said composition is in a form suitable for oral administration.

11/ 12. A controlled-release glucosamine composition of Claim 1, wherein said controlled-release matrix system is capable of releasing said glucosamine at a substantially constant rate over a designated time.

12/ 13. A controlled-release glucosamine composition of Claim ~~12~~¹¹, wherein said designated time period is selected from the group consisting of about 6, 8, 12 and 24 hours.

13/ 14. A controlled-release glucosamine composition of Claim ~~13~~¹², wherein said designated time period is about 12 hours.

14/ 15. A controlled-release glucosamine composition of Claim 1, further comprising a therapeutically effective amount of chondroitin sulfate.

Sub A 2
16. A unit dosage for controlled delivery of glucosamine comprising a glucosamine component dispersed in a controlled-release matrix system comprising a controlled-release component capable of providing a release profile which results in a substantially constant glucosamine release rate over a designated time period.

16/ 17. The unit dosage of Claim ~~16~~¹⁵, which is a tablet.

18. The unit dosage of Claim 17, wherein said tablet comprises HPMC is an amount of from about 8 to about 12 wt%, said HPMC having a molecular weight of about 85,000, and wherein said designated time period is about 12 hours.

19. A method for the treatment of conditions having an inflammatory component comprising:

administering to a human or animal having a condition with an inflammatory component a composition which contains a therapeutically effective amount of a glucosamine component dispersed in a controlled-release matrix system capable of releasing said glucosamine in an amount and at a rate sufficient to maintain an effective glucosamine blood serum level over a designated time period, said controlled-release system comprising a controlled-release component which comprises at least one water soluble cellulose polymer.

20. A method of Claim 19, wherein said glucosamine component is selected from the group consisting of N-acetyl-D-glucosamine, glucosamine hydrochloride, glucosamine sulfate and mixtures thereof.

21. A method of Claim 20, wherein a daily dosage of said glucosamine ranges from about 14 mg to about 29 mg per kilogram of body weight.

22. A method of Claim 21, wherein said composition is in a tablet form.

23. A method of Claim 22, wherein said tablet comprises a high molecular weight HPMC in an amount from about 8 to about 12 wt %.

24. A method of Claim 23, wherein said tablet releases said glucosamine at a substantially constant rate over a designated time period.

25. A method of Claim 24, further comprising:
maintaining a substantially constant glucosamine release rate, by continually repeating the administering step at the expiration of said designated time period, so as to relieve the inflammatory component of said condition.

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26. A method of Claim ~~25~~²⁴, wherein said designated time period is approximately 12 hours.

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H4

27. A composition for the treatment of arthritis without adversely effecting glucose regulation, said composition comprising a therapeutically effective amount of a glucosamine component dispersed in a controlled-release matrix system capable of releasing said glucosamine in an amount and at a rate sufficient to maintain an effective glucosamine blood serum level for treatment of arthritis, but not to exceed a glucosamine blood serum level which will affect an adverse change in glucose regulation, over a designated time period.

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28. A composition of Claim ~~27~~²⁶, wherein said adverse change in glucose regulation is manifested by increased insulin resistance.

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29. A composition of Claim ~~27~~²⁶, wherein said glucosamine component is selected from the group consisting of N-acetyl-D-glucosamine, glucosamine hydrochloride, glucosamine sulfate and mixtures thereof.

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30. A composition of Claim ~~27~~²⁶, wherein a daily dosage of said glucosamine ranges from about 14 mg to about 29 mg per kilogram of body weight.

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31. A composition of Claim ~~27~~²⁶, wherein said rate is less than 100 micrograms/min/kg body weight.

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32. A composition of Claim ~~27~~²⁶, wherein said composition is in a form suitable for oral administration.

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33. A composition of Claim ~~27~~²⁶, wherein said controlled-release matrix system releases said glucosamine at a substantially constant rate over a designated time period.

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34. A composition of Claim ~~33~~³², wherein said composition is in the form of a tablet.

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35. A composition of Claim 34, wherein said tablet comprises a high molecular weight HPMC in an amount from about 8 to about 12 wt %.

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36. A composition of claim 35, wherein said designated time period is approximately 12 hours.

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10 37. A method for the treatment of arthritis without adversely effecting glucose regulation, said method comprising:

administering to a patient having arthritis a composition which comprises a therapeutically effective amount of a glucosamine component for the treatment of arthritis dispersed in a controlled-release matrix system capable of releasing said glucosamine in an amount and at a rate sufficient to maintain an effective glucosamine blood serum level for the treatment of arthritis, but not to exceed a glucosamine blood serum level which will affect an adverse change in glucose regulation, over a designated time period.

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38. A method for the treatment of arthritis of claim 37, wherein said patient has both arthritis and diabetes.

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39. A method for the treatment of arthritis of Claim 37, wherein said adverse change in glucose regulation is manifested by increased insulin resistance.

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40. A method for the treatment of arthritis of Claim 37, wherein said glucosamine component is selected from the group consisting of N-acetyl-D-glucosamine, glucosamine hydrochloride, glucosamine sulfate and mixtures thereof.

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41. A method for the treatment of arthritis of Claim 37, wherein a daily dosage of said glucosamine ranges from about 14 mg to about 29 mg per kilogram of body weight.

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42. A method for the treatment of arthritis of Claim 37, wherein said composition is in a tablet form.

~~43~~ A method for the treatment of arthritis of Claim ~~42~~, wherein said tablet releases said glucosamine at a substantially constant rate over a designated time period.

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44. A method for the treatment of arthritis of Claim 43, wherein said tablet
5 comprises a high molecular weight HPMC in an amount from about 8 to about 12 wt %.

44/45. A method for the treatment of arthritis of claim 43/44, wherein said designated time period is approximately 12 hours.

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46. A method for the treatment of arthritis of Claim 37, wherein said rate is less than 100 micrograms/min/kg body weight.

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47. A method for the treatment of arthritis of Claim 36, further comprising:
maintaining said glucosamine blood serum level, by continually repeating the administering
step at the expiration of said designated time period, so as to relieve the symptoms of
arthritis.

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~~48.~~ A method for the treatment of arthritis of Claim ⁴⁶~~47~~, wherein said designated time period is approximately 12 hours.